

## 5. Current Pending Claims

Claims to all non-elected subject matter are canceled without prejudice.

Applicant specifically reserves all rights to pursue the non-elected subject matter in a subsequent divisional or continuation application.

Claims 1-4, 6-7, 15-24, 31-32, 41 and 57-59 are amended herein and new claims 73-78 are added to be more particularly directed to certain novel embodiments of the present invention. Moreover, the pending claims are directed more particularly to the elected subject matter and avoid dependence upon non-elected claims. All claims are supported by the specification and claims as originally filed and do not add new matter.

In particular, new claims 73 and 74 recite, respectively, an isolated recombinant PMPE polypeptide comprising a polypeptide encoded by a nucleic acid sequence comprising a nucleotide sequence of SEQ ID No.: 1 (Claim 73) and an amino acid sequence comprising SEQ ID No.: 2 (Claim 74), fused to a histidine affinity ((H)<sub>6</sub>) domain. Support for these claims is found, e.g., in the specification in Section 6, in particular in subsections 6.11, 6.13 and 6.15.

Claim 57, as amended, recites culturing an isolated recombinant PMPE polypeptide produced by a method of culturing a host cell containing a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.: 1 fused to a nucleotide sequence encoding a histidine ((H)<sub>6</sub>) domain. Support for this claim is found, e.g., in the specification at page 43, lines, 1-3 and the examples in Section 6, in particular in subsections 6.11, 6.13 and 6.15.

Claim 58, as amended, recites an isolated recombinant PMPE polypeptide produced by a method of culturing a host cell containing plasmid M15 pREP (pQE-pmpE-Ct) #37 obtained from ATCC accession No. PTA-2462 and recovering said recombinant

polypeptide. New claim 76 recites an antigenic composition comprising an isolated PMPE polypeptide encoded by the plasmid M15 pREP (pQE-pmpE-Ct) #37 obtainable from ATCC accession No. PTA-2462. Support is found in Section 5.1, Biological Deposits and in Section 6, in particular subsection 6.11.

Claim 59, as amended, avoids dependence on non-elected Claim 33.

New Claim 75 recites an antigenic composition comprising an adjuvant together with an isolated PMPE polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis, wherein the PMPE polypeptide comprises an amino acid sequence of SEQ ID No.: 2 or a fragment of said PMPE polypeptide which fragment is recognizable by an antibody that binds specifically to a polypeptide comprising an amino acid sequence of SEQ ID No.: 2. Support is found, e.g. in Section 5.7 of the specification.

New Claims 77 and 78, dependent on Claim 31, recite vaccine compositions in which the additional immunogen is, respectively, another protein of *Chlamydia* and HMWP (High Molecular Weight Protein) of *Chlamydia trachomatis*. Support is found e.g., in Section 5, in particular in subsection 5.7.

#### 6. Rejections based on Section 112

Claims 1-7, 15-24, 31-32, 41 and 57-59 are rejected under Section 112, first paragraph as allegedly providing insufficient written description for the full breadth of the claims. The Office Action asserts that only polypeptides of SEQ ID No.: 2 or 4 are described.

Attorney for Applicant respectfully do not agree. In order, however, to more clearly point out and distinctly claim the inventive subject matter, all present claims recite either a polypeptide comprising the amino acid sequence of SEQ ID No.: 2 or a sequence

substantially homologous thereto, a polypeptide comprising an amino acid sequence encoded by a nucleic acid comprising the nucleotide sequence of SEQ ID No.: 1, or a PMPE polypeptide or fragment thereof which specifically binds to an antibody which specifically binds to a protein comprising an amino acid sequence of SEQ ID No.: 2. For reasons set forth below, it is submitted that such subject matter is sufficiently described to meet the statutory written description requirement.

It is noted that the Office Action admits that the specification fully discloses a PMPE polypeptide comprising SEQ ID No.: 2 (or encoded by a nucleic acid comprising SEQ ID No.: 1). Attention is directed to the Example Section of the specification, in particular to Section 6.11 which describes the construction of plasmid M15 pREP (pQE-pmpE-Ct) #37 (said plasmid deposited in *E. coli* and assigned ATCC No. PTA-2462) which contains a nucleic acid insert encoding PMPE. Attention is further directed to Exhibit A submitted herewith. Exhibit A presents the amino acid sequence encoded by the PMPE encoding nucleic acid contained in the plasmid of ATCC No. PTA-2462. In addition, Exhibit A presents a BLAST comparison between the amino acid sequence of SEQ ID No.: 2 and the amino acid sequence encoded by the relevant nucleic acid of the plasmid of ATCC No. PTA-2462. In the BLAST analysis, the sequence labeled query is the sequence of the insert of Plasmid M15pREP (pQE-pmpE-Ct) #37. The sequence labeled "subject" is SEQ ID No.: 2. As shown in the BLAST comparison, the two sequences encoding PMPE are at least 90% identical. The PMPE polypeptide encoded by this plasmid differs from SEQ ID No.: 2 at amino acid residues 1-32, 332 (I(V), 369 (N(S), 613 (T(S), 634 (Q(K), 706 (D(E), 722 (S(F), 775 (T(A), and 899-900 (PG(LE).

Attention is directed to the teaching of the specification in subsection 5.10 relating to the Biological Deposits and to the Statement on Behalf of Applicant (Statement

submitted herewith). As indicated in the specification, the plasmid of ATCC No. PTA-2462 has been submitted in accordance with Budapest Treaty requirements and, as indicated in the Statement, all requirements regarding the availability of said deposit are met.

In view of the above detailed reasons, it is submitted that written description is provided for the full scope of the present claims. Hence, this rejection must be withdrawn.

Claims 15-24,31-32 and 41 are rejected under Section 112, first paragraph, as allegedly not enabled for a vaccine composition. Although the Office Action admits that the specification enables an isolated PMPE protein, it alleges that it does not provide guidance regarding use of the PMPE as a vaccine.

Attorneys for Applicant emphatically disagree. The specification at pages 43-46 teaches methods of administering the claimed PMPE polypeptide or fragments thereof to elicit immune responses to PMPE polypeptide. In addition, the specification at pages 64-66 provides an *in vivo* model to determine the ability of a polypeptide to induce protective immune responses against *C. trachomatis* induced salpingitis and infertility.

Attention is directed to Exhibit B submitted herewith. Exhibit B presents results obtained using the teaching of the specification for use of PMPE to protect against *Chlamydia* using an *in vivo* animal model. Results demonstrating the ability of PMPE to protect C3HeJOUj mice using the procedure disclosed in the specification are shown in Exhibit B. Groups of mice were immunized intranasally (i.n.) with PMPE (with or without AB5 as an adjuvant) prior to challenge with live *C. trachomatis*. Negative control animals were “immunized” with adjuvant alone (AB5) intranasally prior to administration of live *C. trachomatis*. Positive control animals were “immunized” with adjuvant alone intranasally but were not administered live *C. trachomatis*. The fertility rate for mice vaccinated with PMPE or PMPE and adjuvant (AB5) was 50% and 46% respectively. The fertility rate of mice

immunized with adjuvant alone (AB5) was 9% and the fertility of mice not infected with *C. trachomatis* but administered adjuvant (AB5) was 95%. These results demonstrate that PMPE is an effective vaccine for ameliorating infertility induced by infection with *C. trachomatis*. Thus, one with skill in the art would, in light of teaching of the specification, not only be able to make the claimed PMPE polypeptides, determine whether the PMPE polypeptides have the ability to ameliorate disease associated with infection with *C. trachomatis*, but also to use the PMPE polypeptides as a vaccine against *Chlamydia*. Thus, this rejection must be withdrawn.

Claims 1-7, 15-24, 31-32, 41 and 57-59 are rejected under Section 112, second paragraph as indefinite because the abbreviated PMPE is not identified by the full term.

In response, the full term associated with the abbreviation “PMPE” is provided in Claim 1. Hence, this rejection is avoided.

Claim 4 is rejected under Section 112, second paragraph as indefinite because it is alleged that the metes and bounds of the term “substantially” are not clear.

Applicant respectfully disagrees. Claim 4 is drawn to polypeptides which are “substantially homologous” to SEQ ID NO:2. The specification on page 12, line 23 through page 14, line 30, discloses the metes and bounds of the term “substantially homologous.” In fact, the specification discloses that a sequence is “substantially homologous” if it is at least 70%, 80% or 90% identical to the reference protein using any of the algorithms disclosed in the specification on pages 12-14. Further, the specification teaches how to determine the percent identity of two sequences by comparing the sequences and that in calculating percent identity, only exact matches are counted (see page 14, at lines 31-33 and page 13, lines 22-32). Moreover, Claim 4, is amended herein to incorporate the teaching of the specification at pages 12-14 and thus, as amended, recites the specification’s definition of

the term “substantially homologous” in place of the actual term. This is a non-limiting amendment as it only substitutes the specification’s definition for the term itself. Hence, this rejection is in error and should be withdrawn.

#### 7. Rejections Based on Section 102

Claims 1-7 are rejected under Section 102 as anticipated by Stephens et al. 1998, Science 282: 75-4-75 (Stephens).

The Office Action alleges that the instantly claimed polypeptides are anticipated by Stephens because Stephens teaches a protein that is 98% identical to SEQ ID NO:2 of the claimed invention.

Attorneys for Applicant respectfully disagree. Stephens teaches the sequence of the *Chlamydial* genome and presents analysis of the genome to determine “likely protein coding genes” with “inferred functional assignment” ( see page 7554, third column). Stephens identifies a total of nine genes alleged as encoding putative PMP (polymorphic membrane proteins), including a gene encoding a protein which is 98% identical to SEQ ID NO:2. Stephens also teaches that relatively little is known regarding the *Chlamydial* outer membrane and that PMPE has “attributes” of outer membrane proteins. Thus Stephens at most discloses the theoretical existence and function of a gene encoding PMPE but does not provide any evidence that a protein with sequence homology to SEQ ID NO:2 of the present application is in fact transcribed by *Chlamydia trachomatis*, much less that such protein was obtained in isolated form. Importantly, Stephens does not teach or suggest any use for the putative PMPE and does not provide any evidence that PMPE can be used as a vaccine to ameliorate disease caused by infection with *Chlamydia*.

In order for a reference to anticipate a claimed invention, the reference must teach each element of the claimed invention. With respect to claims directed to the full length isolated PMPE polypeptide, Stephens discloses no such isolated protein. With respect to claims directed to peptide fragments of PMPE, Stephens teaches no fragments of any proteins. Claims 6 and 7 are not directed to full length PMPE polypeptide since the term “fragment” can not read upon the full length protein. Stephens does not teach any of the fragments encompassed by the claims and does not teach or suggest fragments comprising SEQ ID NOS: 5-24. Stephens does not teach a composition comprising an isolated PMPE polypeptide fused to an amino acid sequence comprising a histidine ((H)<sub>6</sub>) affinity domain. Hence, Stephens does not anticipate Claims 57, 58, or new Claims 73, 74 or 76. Finally, Stephens does not teach or suggest a vaccine composition comprising PMPE or fragment of PMPE with a pharmaceutically acceptable carrier or diluent ( as is claimed in claims 15 and 20) or a composition comprising PMPE and an adjuvant or immunostimulatory compound ( as is claimed in claims 16-19 and claims 21-24).

Thus Stephens is not an enabling disclosure of isolated PMPE polypeptides of the presently claimed invention and does not anticipate the claimed invention. For all the above reasons, this rejection should be withdrawn.

Claims 15-24, 31-32 and 41 are rejected under Section 102(a) as anticipated by PCT Publication No. 0113448 by Probst et al. (Probst) published June 15, 2000.

The Office Action alleges that the claims are anticipated by Probst et al. WO 00/34483 published June 15, 2000. (Probst)

Attorney’s for Applicant respectfully disagree. Firstly, it is submitted that Probst is not available as prior art to the present claims. Attention is directed to the Declaration under 37 C.F.R. §1.131 of Dr. W. James Jackson (Jackson Declaration) inventor of the present application, submitted herewith with attached Exhibits 1-12-C. The Jackson Declaration clearly evidences, that prior to the effective date of Probst, i.e. June 15, 2000, Applicant had conceived of a vaccine composition comprising an isolated or recombinant

PMPE of *Chlamydia* of between 90 and 115 kDa. Attention is directed to Exhibits 1-12-C attached to the Jackson Declaration, to the explanation relating to the Exhibits in paragraphs 4 to 9 of the Jackson Declaration and to the conclusion affirmed by Dr. Jackson in paragraph 9. Hence, Probst is not available as prior art.

Secondly, even if assuming *arguendo*, Probst were available as prior art, Applicant submits that this reference does not anticipate the claimed subject matter. Probst describes 293 sequences, one of which is SEQ ID NO:177 which is 98.1% homologous to SEQ ID NO:2. Probst further teaches that PMPE contains “predictable signal peptides” and alleges that such evidence “suggests” that it is an outer membrane protein ( see Probst page 67, lines 13-14 and page 68, line 14-17). Thus Probst merely teaches a theoretical existence and function of gene encoding PMPE but does not provide any evidence that a protein with sequence homology to SEQ ID NO:2 of the instant application is in fact transcribed by *Chlamydia trachomatis* or that the protein even is, in fact, an outer membrane protein. Probst does not provide an enabling disclosure of how to obtain PMPE comprising SEQ ID NO: 2. Importantly Probst does not provide any evidence that PMPE can be used as a vaccine to ameliorate disease caused by infection with *Chlamydia*.

In order for a reference to anticipate the claimed invention, the reference must teach and, in fact, enable each element of the claimed invention. Probst does not describe actual preparation of a vaccine composition comprising PMPE or a fragment of PMPE with a pharmaceutically acceptable carrier or diluent ( as is claimed in claims 15 and 29 or a composition comprising PMPE and an adjuvant or immunostimulatory compound ( as is claimed in claims 16-19 and claims 21-24).

Thus Probst is not an enabling disclosure of PMPE polypeptides of the instantly




claimed invention and does not anticipate the claimed invention. For all the above reasons the rejection should be withdrawn.

It has come to the attention of Applicant, that the first priority application relied upon by Probst has issued as U.S. Patent No. 6,166,177. A copy is submitted herewith indicated as Reference BB. Reference BB does not teach the presently claimed subject matter.

Accordingly, in view of all the remarks above and the evidence in the Jackson Declaration, it is submitted that the claims are in form for allowance.

Respectfully submitted,

Date December 3, 2001

  
Geraldine F. Baldwin (Reg. No.) 31,232

**PENNIE & EDMONDS LLP**  
1155 Avenue of the Americas  
New York, New York 10036-2711  
(212) 790-9090



Appendix A

*Marked-Up Version of the Specification*  
*Application No: 09/677,752*

[Deletion indicated by square brackets and addition indicated by double underlining]

Page 10, starting at line 27:

Figure 5 A-E. Full length nucleotide sequence and corresponding deduced amino acid sequence of the PMPE polypeptide of *Chlamydia trachomatis* L2.

Figure 6 A-E. Full length nucleotide sequence and corresponding deduced amino acid sequence of the PMPI polypeptide of *Chlamydia trachomatis* L2.

Page 12, starting at line 23:

As used herein a "substantially homologous" sequence is at least 70%, preferably greater than 80%, more preferably greater than 90% identical to a reference amino acid or nucleotide sequence of identical size or when compared to a reference sequence when the alignment or comparison is conducted by a computer homology program or search algorithm known in the art. By way of example and not limitation, useful computer homology programs include the following: Basic Local Alignment Search Tool (BLAST) [(www.ncbi.nlm.nih.gov)] (Altschul et al., 1990, J. of Molec. Biol., 215:403-410, "The BLAST Algorithm"; Altschul et al., 1997, Nuc. Acids Res. 25:3389-3402) a heuristic search algorithm tailored to searching for sequence similarity which ascribes significance using the statistical methods of Karlin and Altschul 1990, Proc. Nat'l Acad. Sci. USA, 87:2264-68; 1993, Proc. Nat'l Acad. Sci. USA 90:5873-77. Five specific BLAST programs perform the following tasks:

Page 13, starting at line 11:

Smith-Waterman (database: European Bioinformatics Institute [www.ebi.ac.uk/bic\_sw/]) (Smith-Waterman, 1981, J. of Molec. Biol., 147:195-197) is a mathematically rigorous algorithm for sequence alignments.

Page 13, starting at line 14:

FASTA (see Pearson et al., 1988, Proc. Nat'l Acad. Sci. USA, 85:2444-2448) is a heuristic approximation to the Smith-Waterman algorithm. For a general discussion of the procedure and benefits of the BLAST, Smith-Waterman and FASTA algorithms see Nicholas et al., 1998, "A Tutorial on Searching Sequence Databases and Sequence Scoring Methods" [(www.psc.edu)] and references cited therein.

Page 13-14, starting at page 13, line 33:

The determination of percent identity between two sequences can be accomplished using a mathematical algorithm, a preferred, non-limiting example of a mathematical algorithm utilized for the comparison of two sequences is the algorithm of Karlin and Altschul, 1990, Proc. Nat'l Acad. Sci. USA, 87:2264-68; as modified by 1993, Proc. Nat'l Acad. Sci. USA 90:5873-77. Such algorithm is incorporated into the NBLAST and XBLAST programs of Altschul, 1990, J. of Molec. Biol., 215:403-410. BLAST nucleotide searches can be performed with the NBLAST program, score = 100, wordlength = 12 to obtain nucleotide sequences homologous to a nucleic acid molecule of the invention. BLAST protein searches can be performed with the XBLAST program, score = 50, wordlength = 3 to obtain amino acid sequences homologous to a protein molecule of the invention. To obtain gapped alignments for comparison purposes, Gapped BLAST can be utilized as described in Altschul, 1997, Nuc. Acids Res. 25:3389-3402. Alternatively, PSI-BLAST can be used to perform an iterated search which detects distant relationships between molecules (*Id.*). When utilizing BLAST, Gapped BLAST, and PSI-BLAST programs, the default parameters of the respective programs can be used. Another preferred, non-limiting example of a mathematical algorithm utilized for the comparison of sequences is the algorithm of Myers and Miller, CABIOS (1989). Such an algorithm is incorporated into the ALIGN program (version 2.0) which is part of the CGC sequence alignment software package. When using the ALIGN program for comparing amino acid sequences, a PAM120 weight residue table, a gap length penalty of 12, and a gap penalty of 4 can be used. Additional algorithms for sequence analysis are known in the art and include ADVANCE and ADAM as described in Torellis and Robotti (1994) Comput. Appl. Biosc., 10:3-5; and FASTA described in Pearson and Lipman, 1988, Proc. Nat'l Acad. Sci. USA, 85:2444-2448. Within FASTA, ktup is a control option that sets the sensitivity and speed of the search. If

ktup = 2, similar regions in the two sequences being compared are found by looking at pairs of aligned residues; if ktup = 1, single aligned amino acids are examined. Ktup can be set to 2 or 1 for protein sequences, or from 1 to 6 for nucleotide sequences. The default, if ktup is not specified, is 2 for proteins and 6 for nucleotides. For a further description of FASTA parameters[, see <http://bioweb.pasteur.fr/docs/man/man/fasta.1.html#sect2>, the contents of which are incorporated herein by reference]. Alternatively, protein sequence alignment may be carried out using the CLUSTAL W algorithm as described by Higgins et al., 1996, Methods Enzymol., 266:383-402.

Page 58, starting at line 4:

<u>Plasmid</u>	<u>ATCC Accession No.</u>	<u>Date Deposited</u>
M15 pREP (pQE-pmpE-Ct)#37	ATCC PTA-2462	Sept. 12, 2000
TOP10(pBAD-pmpI-Ct-Uni)#7	ATCC PTA-2461	Sept. 12, 2000

Appendix B

*Marked-up Version of the Amended Claims*  
*Application No. 09/677,762*

[Underlining indicates addition and square brackets indicate deletion]

1. (Once amended) An isolated putative membrane protein E (PMPE) [or PMPI] polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis which protein specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.

2. (Once amended) The PMPE [or PMPI] polypeptide of claim 1, wherein the *Chlamydia spp.* is *Chlamydia trachomatis*, *Chlamydia pneumonia*, *Chlamydia psittaci* or *Chlamydia pecorum*.

3. (Once amended) The PMPE [or PMPI] polypeptide of claim 2, wherein the *Chlamydia spp.* is *C. trachomatis*.

4. (Once amended) The PMPE [or PMPI] polypeptide of claim 1, which comprises an amino acid sequence of SEQ ID NO.:2, a sequence [substantially homologous] at least 70% identical thereto when % identity is determined using XBLAST program, score=50, wordlength=3, or an at least 8 amino acid fragment thereof which fragment specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.

6. (Once amended) A peptide fragment of the PMPE [or PMPI] polypeptide of claim 1, which fragment is at least 8 amino acids in length and specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.

7. (Once amended) The peptide fragment of claim 6 wherein said peptide fragment comprises the amino acid sequence of one of SEQ ID NO.:5-[34]22.

15. (Once amended) A vaccine comprising a PMPE [or PMPI] polypeptide of claim 1 and a pharmaceutically acceptable carrier or diluent.

31. (Once amended) The vaccine of any one of claims 15 or 20[, 20 or 25] additionally comprising one or more immunogens selected from the group consisting of a lipid, lipoprotein, phospholipid, lipooligosaccharide, protein, attenuated organism and inactivated whole cell.

41. (Once amended) A vaccine comprising one or more of an isolated PMPE [or PMPI] polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined in SDS polyacrylamide gel electrophoresis; or an isolated nucleic acid comprising a nucleotide sequence encoding an PMPE [or PMPI] polypeptide of a *Chlamydia spp.*, said PMPE [or PMPI] polypeptide having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis; said vaccine further comprising one or more adjuvants or immunostimulatory compounds selected from the group consisting of alum, MLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

57. (Once amended) An isolated recombinant PMPE [or PMPI] polypeptide produced by a method comprising culturing [the transformed] a host cell [of Claim 54] containing a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.:1 fused to a nucleotide sequence encoding a histidine affinity ((H)<sub>6</sub>) domain under conditions suitable for expression of said PMPE [or PMPI] polypeptide and recovering said recombinant PMPE [or PMPI] polypeptide.

58. (Once amended) An isolated recombinant PMPE [or PMPI] polypeptide produced by a method comprising culturing a [the transformed] host cell [of Claims 55] containing plasmid M15 pREP (pQE-pmpE-Ct) #37 obtainable from *E.coli* having ATCC accession No. PTA-2462 under conditions suitable for expression of said PMPE [or PMPI] polypeptide and recovering said recombinant PMPE [or PMPI] polypeptide.

59. (Once amended) An isolated PMPE [or PMPI] polypeptide produced by a method comprising culturing a [the] host cell [of Claim 56] containing a nucleic acid molecule comprising a nucleotide sequence which encodes a PMPE comprising an amino acid sequence of SEQ ID No.: 2 under conditions suitable for the expression of a PMPE [or PMPI] polypeptide and recovering said PMPE [or PMPI] polypeptide.

**Appendix C**

***Pending Claims in  
Application No. 09/677,752  
upon entry of amendment***

1. (Once amended) An isolated putative membrane protein E (PMPE) polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis which protein specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.
2. (Once amended) The PMPE polypeptide of claim 1, wherein the *Chlamydia spp.* is *Chlamydia trachomatis*, *Chlamydia pneumonia*, *Chlamydia psittaci* or *Chlamydia pecorum*.
3. (Once amended) The PMPE polypeptide of claim 2, wherein the *Chlamydia spp.* is *C. trachomatis*.
4. (Once amended) The PMPE polypeptide of claim 1, which comprises an amino acid sequence of SEQ ID NO.:2, a sequence at least 70% identical thereto when % identity is determined using XBLAST program, score=50, wordlength=3, or an at least 8 amino acid fragment thereof which fragment specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.



6. (Once amended) A peptide fragment of the PMPE polypeptide of claim 1, which fragment is at least 8 amino acids in length and specifically binds an antibody that specifically binds to a protein comprising the amino acid sequence of SEQ ID No.: 2.

7. (Once amended) The peptide fragment of claim 6 wherein said peptide fragment comprises the amino acid sequence of one of SEQ ID NO.:5-22.

15. (Once amended) A vaccine comprising a PMPE polypeptide of claim 1 and a pharmaceutically acceptable carrier or diluent.

16. The vaccine of claim 15 further comprising one or more adjuvants or immunostimulatory compounds.

17. The vaccine of claim 16 wherein the adjuvants or immunostimulatory compounds are one or more of alum, MLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

18. The vaccine of claim 16 comprising one adjuvant or immunostimulatory compound.

19. The vaccine of claim 16 comprising two different adjuvants or immunostimulatory compounds.

20. A vaccine comprising the polypeptide fragment of claim 6 and a pharmaceutically acceptable carrier or diluent.

21. The vaccine of claim 20 further comprising one or more adjuvants or immunostimulatory compounds.

22. The vaccine of claim 21 wherein the one or more adjuvants or immunostimulatory compounds are selected from the group consisting of alum, MLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

23. The vaccine of claim 21 comprising one adjuvant or immunostimulatory compound.

24. The vaccine of claim 21 comprising two different adjuvants or immunostimulatory compounds.

31. (Once amended) The vaccine of any one of claims 15 or 20 additionally comprising one or more immunogens selected from the group consisting of a lipid, lipoprotein, phospholipid, lipooligosaccharide, protein, attenuated organism and inactivated whole cell.

32. The vaccine of claim 31 wherein the one or more immunogens are a DPT vaccine, a HMWP of *C. trachomatis*, a MOMP of *C. trachomatis*, or an entire organism, or subunit therefrom, of *Chlamydia*, *Neisseria gonorrhea*, HIV, *Haemophilus influenzae*,

*Moraxella catarrhalis*, *Human papilloma virus*, *Herpes simplex virus*, *Haemophilus ducreyi*, *Treponema pallidum*, *Candida albicans* or *Streptococcus pneumoniae*.

41. (Once amended) A vaccine comprising one or more of an isolated PMPE polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined in SDS polyacrylamide gel electrophoresis; or an isolated nucleic acid comprising a nucleotide sequence encoding an PMPE polypeptide of a *Chlamydia spp.*, said PMPE polypeptide having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis; said vaccine further comprising one or more adjuvants or immunostimulatory compounds selected from the group consisting of alum, MLT, QS21, MF59, CpG DNA, PML, calcium phosphate and PLG.

57. (Once amended) An isolated recombinant PMPE polypeptide produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.:1 fused to a nucleotide sequence encoding a histidine affinity ((H)<sub>6</sub>) domain under conditions suitable for expression of said PMPE polypeptide and recovering said recombinant PMPE polypeptide.

58. (Once amended) An isolated recombinant PMPE polypeptide produced by a method comprising culturing a host cell containing plasmid M15 pREP (pQE-pmpE-Ct) #37 obtainable from *E.coli* having ATCC accession No. PTA-2462 under conditions suitable for expression of said PMPE polypeptide and recovering said recombinant PMPE polypeptide.

59. (Once amended) An isolated PMPE polypeptide produced by a method comprising culturing a host cell containing a nucleic acid molecule comprising a nucleotide sequence which encodes a PMPE comprising an amino acid sequence of SEQ ID No.: 2 under conditions suitable for the expression of a PMPE polypeptide and recovering said PMPE polypeptide.

73. (New) An isolated recombinant PMPE polypeptide comprising a polypeptide encoded by a nucleic acid molecule comprising the nucleotide sequence of SEQ ID No.: 1 fused to a nucleic acid molecule encoding histidine affinity ((H)<sub>6</sub>) domain.

74. (New) An isolated recombinant PMPE polypeptide comprising an amino sequence of SEQ ID No.: 2 fused to an amino acid sequence comprising a histidine affinity ((H)<sub>6</sub>) domain.

75. (New) An antigenic composition comprising an isolated PMPE polypeptide of a *Chlamydia spp.*, having a molecular weight between 90 and 115 kDa as determined by SDS polyacrylamide gel electrophoresis, wherein the PMPE polypeptide comprises an amino acid sequence of SEQ ID No.: 2 or a fragment of said PMPE polypeptide which fragment is recognizable by an antibody that binds specifically to a polypeptide comprising an amino acid sequence of SEQ ID No.: 2, together with an adjuvant.

76. (New) An antigenic composition comprising an isolated PMPE polypeptide of a *Chlamydia spp.* having a molecular weight between 90 and 115 Kda as determined by SDS polyacrylamide gel electrophoresis wherein the PMPE polypeptide

comprises an amino acid encoded by the plasmid M15 pREP (pQE-pmpE-Ct) #37 obtainable from *E. coli* having ATCC accession No. PTA-2462.

77. (New) The vaccine of Claim 31, wherein the additional immunogen is another protein of *Chlamydia*.

78. (New) The vaccine of Claim 31, wherein the additional immunogen is HMWP (High Molecular Weight Protein) of *Chlamydia trachomatis*.